REMARKS

Claims 1-3, 7-20, 22-30, 32, 33 and 35 are pending in this application. Claims 3 and 30 withdrawn from consideration. By this Amendment, claims 1, 28 and 32 are amended, and claims 4-6, 21, 31 and 34 are cancelled. No new matter is added by this Amendment. Support for the language added to claims 1 and 28 can be found in original claims 21 and 34, respectively, original claim 32 and throughout the specification.

I. Claim Objection

Claim 1 was objected to for allegedly not being in active language. To expedite the prosecution of this application, Applicants have amended claim 1 as suggested by the Patent Office to recite "incubating the cellular material."

Applicants submit that this objection is now moot. Reconsideration and withdrawal of the rejection are respectfully requested.

II. Rejections Under 35 U.S.C. §102

A. Gilles

Claims 1, 2, 4-6, 8-29 and 31-35 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Gilles et al., "Effect of Compensatory Organic Osmolytes on Resistance to Freeze-Drying of L929 Cells and of Their Isolated Chromatin," Comparative Biochemistry and Physiology, Part A 122, pp. 145-55 (1999) (hereinafter "Gilles").

The Patent Office alleges that Gilles teaches a method comprising incubating L929 cells in a culture medium containing 0.3M sucrose for the time it takes for 10 passages, adding trehalose to the medium prior to freezing and drying. Applicants respectfully disagree with the Patent Office's assertion that Gilles teaches or suggests all of the features recited in the present claims.

Applicants submit that Gilles does not teach or suggest that the at least one sugar comprises trehalose as recited in claim 1, or that the at least one polysaccharide comprises

trehalose as recited in claims 28. Instead, Gilles teaches that cells are cultured in DMEM medium supplemented with 300 mM sorbitol, proline, or sucrose.

Gilles nowhere teaches or suggests (1) incubating cellular material in a culture medium containing at least one sugar, wherein the at least one sugar comprises trehalose, as recited in claim 1, or (2) incubating the cellular material in a culture medium containing at least one polysaccharide, wherein the at least one polysaccharide comprises trehalose, as recited in claim 28.

For the foregoing reasons, Applicants submit that Gilles does not teach or suggest all of the features recited in claims 1, 2, 8-20 and 22-27. Reconsideration and withdrawal of the rejection are thus respectfully requested.

B. Crowe

Claims 1, 2, 4-11, 15-20, 23-29 and 31-33 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 6,771,478 (hereinafter "Crowe"). This rejection is respectfully traversed.

Applicants point out that claim 1 has been amended to incorporate the subject matter of original claim 21. As claim 21 was not rejected in view of Crowe, Applicants submit that claims 1, 2, 4-11, 15-20 and 23-27 are patentable over Crowe.

The rejection under 35 U.S.C. §103(a) relying upon Crowe is more fully discussed below.

For the foregoing reasons and the reasons below, Applicants submit that Crowe does not teach or suggest all of the features recited in claims 1, 2, 7-11, 15-20, 23-29, 32 and 33. Reconsideration and withdrawal of the rejection are thus respectfully requested.

C. Scannell

Claims 28, 29, 31 and 32 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Scannell et al., "The Regulation of Carbohydrate Metabolism in Animal Cells:

Growth on Starch and Maltose," Biochemical Society Transactions 8 (5), pp. 633-4 (1980) (hereinafter "Scannell"). This rejection is respectfully traversed.

Applicants point out that claim 28 has been amended to incorporate the subject matter of original claim 34. As claim 34 was not rejected in view of Scannell, Applicants submit that claims 28, 29, 31 and 32 are patentable over Scannell.

The rejection under 35 U.S.C. §103(a) relying upon Scannell is more fully discussed below.

For the foregoing reasons and reasons below, Applicants submit that Scannell does not teach or suggest all of the features recited in claims 28, 29 and 32. Reconsideration and withdrawal of the rejection are thus respectfully requested.

III. Rejections Under 35 U.S.C. §103(a)

A. Kim

Claims 1, 2, 4-14, 17-29 and 31-35 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kim et al., "Cryopreservation of Taxus Chinensis Suspension Cell Cultures," CryoLetters 22, pp. 43-50 (2001) (hereinafter "Kim"). This rejection is respectfully traversed.

The Patent Office alleges that Kim teaches a method comprising incubating a cell culture of *T. chinensis* in a culture medium comprising 1 M trehalose for 30 minutes and then freezing. The Patent Office admits that Kim does not teach incubation for at least three hours, but alleges that it would have been obvious to incubate for three hours because incubation for 30 minutes was shown to increase viability. Applicants respectfully disagree with the Patent Office's allegations.

Applicants submit that Kim does not teach or suggest (1) incubating the cellular material in a culture medium containing at least one sugar for at least three hours, wherein the culture medium contains from 0.1 to 0.4 M sugar, and wherein the at least one sugar

comprises trehalose, as recited in claim 1, or (2) incubating the cellular material in a culture medium containing at least one polysaccharide, wherein the culture medium contains from 0.1 to 0.4 M polysaccharide, and wherein the at least one polysaccharide comprises trehalose, as recited in claim 28.

Kim teaches that suspension cell cultures were maintained in a modified B5 medium supplemented with 1 g/L casein hydrolysate, 30 g/L sucrose (which is significantly greater than 0.10 to 0.4 M sugar in the culture medium, as required in claim 1), 10 μM NAA and 0.2 μM BA. See second full paragraph on page 44 of Kim. To improve the viability of *T. chinensis* suspension cells after freezing and thawing, four kinds of 1 M sugar and sugar alcohols were added to the cryoprotectant solution. See first full paragraph on page 47 of Kim.

Applicants thus submit that Kim does not teach or suggest adding trehalose in concentrations of 0.1 to 0.4 M to the culture medium as required in the present claims. Kim teaches that during incubation, sucrose, not trehalose, may be added to the culture medium. Instead, Kim teaches adding greater amounts of trehalose to the cryoprotectant solution, after freezing and thawing.

Applicants thus submit that Kim does not teach or suggest incubating the cellular material in a culture medium having 0.1 to 0.4 M sugar, wherein the at least one sugar comprises trehalose, as recited in claim 1, or incubating the cellular material in a culture medium having 0.1 to 0.4 M polysaccharide, wherein the polysaccharide comprises trehalose, as recited in claim 28.

For the foregoing reasons, Applicants submit that Kim does not teach or suggest all of the features recited in claims 1, 2, 6-14, 17-20 and 22-27. Reconsideration and withdrawal of the rejection are thus respectfully requested.

B. Gilles

Claims 1, 2, 4-29 and 31-35 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Gilles. This rejection is respectfully traversed.

As discussed in detail above, Gilles does not teach or suggest that the cellular material is viable after preservation, as required in the present claims. For the reasons set forth above, Applicants submit that Gilles does not teach or suggest all of the features recited in claims 1, 2, 6-20 and 22-29. Reconsideration and withdrawal of the rejection are thus respectfully requested.

C. Crowe

Claims 1, 2, 4-29 and 31-35 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Crowe. This rejection is respectfully traversed.

The Patent Office alleges that Crowe, in examples 7-9, teaches a method of incubating a cell in culture medium with 90 mM trehalose for 24 hours. The cells are then allegedly harvested and resuspended in 150 mN trehalose, frozen and dried. The Patent Office further alleges that Crowe teaches a method of cell preservation where cells are incubated in a medium containing a concentration of trehalose and the loading medium is from about 10 mM to about 1.5 M. Applicants respectfully disagree with the Patent Office's allegations.

As explained above, claims 1 and 28 have been amended to incorporate claims 21 and 34, respectively. Applicants submit that Crowe does not teach or suggest incubating the cellular material in a culture medium that contains from 0.10 to 0.4 M sugar, as now required in claim 1.

Applicants submit that Crowe clearly teaches that the amount of preferred trehalose, i.e., sugar, loaded into platelets (corresponding to cellular material) is from about 10 mM to about 50 mM and is achieved by incubating the platelets with a trehalose solution that has up

to 50 mM trehalose therein. Higher concentrations of trehalose during incubation are not preferred. See column 12, line 64 to column 13, line 3 of Crowe.

Crowe clearly teaches against increasing the concentrations of trehalose during incubation. In fact, Crowe teaches that endocytotic uptake route is blocked at sugar concentrations above 0.1 M. Consequently, Crowe prefers not to use sugar concentrations higher than about 50 mM. See column 14, line 16-19.

Although the Patent Office alleges that Crowe teaches a loading medium having from 10 mM to 1.5 M trehalose, this refers to the cryopreservation medium (see column 18, lines 56-62 of Crowe), not the concentration of trehalose in the culture medium as required in claim 1.

Applicants thus submit that Crowe does not teach or suggest incubating the cellular material in a culture medium that contains from 0.10 to 0.4 M sugar, as required in claim 1.

For the foregoing reasons, Applicants submit that Crowe does not teach or suggest all of the features recited in claims 1, 2, 4-20 and 22-27. Reconsideration and withdrawal of the rejection are thus respectfully requested.

D. Toner and Crowe

Claims 1, 2, 4-29 and 31-35 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Publication No. 2005-0277107 (hereinafter "Toner") in combination with Crowe. This rejection is respectfully traversed.

The Patent Office alleges that Toner teaches all of the features recited in the present claims, except for incubating the cells for greater than three hours. The Patent Office thus introduces Crowe as allegedly teaching this feature.

Applicants submit that Toner is not a proper prior art reference as the subject matter claimed in the present application was invented prior to July 26, 2002, the earliest U.S. filing date of Toner. To this end, enclosed herewith is a Declaration Under 37 C.F.R. §1.131,

demonstrating that the presently claimed subject matter was invented prior the invention disclosed in Toner.

As explained above, Crowe alone does not teach or suggest all of the features recited in the present claims. Reconsideration and withdrawal of the rejection are thus respectfully requested.

E. Scannell

Claims 28, 29 and 31-35 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Scannell. This rejection is respectfully traversed.

The Patent Office alleges that Scannell teaches a method of incubating cells for 10 days in 5 mM trehalose. The Patent Office further alleges that one of ordinary skill in the art may increase the concentration of the polysaccharide as this is allegedly an element of experimental design. Applicants respectfully disagree with this allegation.

Although Scannell teaches that CHO-K1 cells may be grown in a culture having a small amount of trehalose (5 mM), Scannell further teaches that the rate of glucose liberation from trehalose was growth-limiting. See paragraph 2 of Scannell. In other words, the trehalose did not support the cells in cell culture. Moreover, Scannell teaches that no trehalose-utilizing mutants were isolated during their research. See paragraph 4 of Scannell.

Applicants thus submit that one of ordinary skill in the art would not have been motivated to modify Scannell by increasing the concentration of trehalose because Scannell teaches that a much smaller amount of trehalose (5 mM) does not support the cells in cell culture. In other words, Scannell teaches away from using trehalose in greater amounts, such as from 0.1 to 0.4 M polysaccharide, as required in claim 28, because trehalose does not support the cells in cell culture.

For the foregoing reasons, Applicants submit that Scannell does not teach or suggest all of the features recited in claims 28, 29, 32, 33 and 35. Reconsideration and withdrawal of the rejection are thus respectfully requested.

F. Burger

Applicants point out that claims 28-35 have been cancelled. Applicants thus submit that this rejection is now moot. Reconsideration and withdrawal of the rejection are thus respectfully requested.

The Patent Office alleges that Burger teaches a method of incubating cells in a culture media comprising 5% trehalose for 30, 60 and 90 minutes. The Patent Office further alleges that one of ordinary skill in the art would have been motivated to substitute the recited concentration of trehalose and the recited incubation time. Applicants respectfully disagree.

As admitted by the Patent Office, Burger does not teach or suggest incubating the cellular material in a culture medium containing at least one polysaccharide for at least three hours, wherein said culture medium contains from 0.1 to 0.4 M polysaccharide, and wherein the at least one polysaccharide comprises trehalose, as required in claim 28. Applicants submit that contrary to the Patent Office's allegations, one of ordinary skill in the art would not have been motivated to incubate the cellular material for at least three hours as recited in claim 28.

Burger teaches that "above that one hour of incubation was found to be sufficient to establish an equilibrium level intracellular; accordingly, the values for 90 minute incubation did not differ from the results presented." See the second full paragraph in the second column on page 235 and Fig. 1 of Burger. In other words, Burger teaches that there is no benefit to incubating the cellular material for greater than one hour.

As such, Applicants submit that Burger teaches away from incubating the cellular material in the culture medium for at least three hours, as required in claim 28.

For the foregoing reasons, Applicants submit that Burger does not teach or suggest all of the features recited in claims 28-30, 32, 33 and 35. Reconsideration and withdrawal of the rejection are thus respectfully requested.

IV. Rejoinder

Applicants submit that upon search, examination and allowance of generic claims 1, 7-19, 22-24, 26 and 27, search and examination should continue as to the non-elected claims 3 and 30, until all claims have been considered and similarly allowed.

V. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1-3, 7-20, 22-30, 32, 33 and 35 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

Leana Levin

William P. Berridge
Registration No. 30,024

Leana Levin
Registration No. 51,939

WPB:LL/hs

Attachment:
Declaration Under 37 C.F.R. §1.131

Date: July 17, 2006

OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400

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